## 510(k) Summary

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| **Prepared:** | March 8, 2013 |
| **Submitter:** | Ingen Orthopedics, LLC<br>2650 US Highway 130<br>Cranbury, NJ 08512 |
| **Contact:** | Perry A. Geremakis<br>President, Chief Executive Officer<br>Ingen Orthopedics, LLC<br>P: 609/409-3316<br>F: 609/409-3317<br>E: pgeramakis@ingenortho.com |
| **Proprietary Name:** | SEVIIN Surface Replacement Shoulder |
| **Common Name:** | Resurfacing Shoulder Prosthesis |
| **Classification Names:** | 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II<br><br>21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II |
| **Product Codes:** | HSD, KWS, KWT |
| **Substantially Equivalent Devices:** | Copeland MB Resurfacing Humeral Heads, K010657, cleared Sept 14, 2001<br><br>Tornier Aequalis Resurfacing Head, K062661, cleared December 22, 2006 |

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**Device Description:**

The SEVIIN Surface Replacement Shoulder is a hemi or total shoulder prosthesis designed for use in patients where the humeral head and neck are of sufficient bone stock and there is an intact or reconstructable rotator cuff. The design requires minimal bone resection, thus giving the patient an alternative to other total shoulder designs where more bone is removed. Additionally, the SEVIIN Surface Replacement Shoulder can be revised to a longer stemmed total shoulder if necessary.

The Resurfacing Humeral Heads are manufactured from Co-Cr-Mo alloy conforming to ASTM F799 and have a polished spherical surface for articulation. The inner surface of the humeral heads is coated with titanium plasma spray. Three sizes of humeral heads are available: 42mm, 48mm and 52mm diameter with a stem that is tapered and fluted to provide stability in the humerus.

The Surface Replacement humeral heads are compatible with the previously cleared SEVIIN Total Shoulder Glenoids (K043346) for total shoulder replacement.

**Intended Use / Indications:**

The SEVIIN Surface Replacement Shoulder is indicated for hemi or total shoulder replacement in patients where the humeral head and neck are of sufficient bone stock and there is an intact or reconstructable rotator cuff.

Hemi or total shoulder replacement is indicated to relieve severe pain or significant disability caused by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease (osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Humeral head fractures
- Traumatic arthritis

The SEVIIN Resurfacing Humeral Heads are intended for cemented and uncemented applications. The glenoid components, when used, are intended for cemented use only.

**Summary of Technologies/Substantial Equivalence:**

The SEVIIN Surface Replacement Shoulder is substantially equivalent to the predicate devices in regards to its intended use and indications, materials, size ranges, and design intent. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

**Non-Clinical Testing:**

Substantial equivalence analysis and torsional testing of the Resurfacing Humeral Head fixation indicate that all components are adequate for their intended use. Substantial equivalence was based on a comparison of intended use, indications, materials, sizes and design.

**Clinical Testing:**

Clinical testing was not necessary to demonstrate substantial equivalence of the SEVIIN Surface Replacement Shoulder to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2013

Ingen Orthopedics, LLC
% Mr. Perry Geremakis
President, Chief Executive Officer
2650 US Highway 130
Cranbury, New Jersey 08512

Re: K130635
Trade/Device Name: SEVIIN Surface Replacement Shoulder
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD, KWS, KWT
Dated: June 26, 2013
Received: July 18, 2013

Dear Mr. Geremakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K130635

**Device Name:** SEVIIN Surface Replacement Shoulder

**Indications for Use:**

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- Rheumatoid arthritis
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**Prescription Use** X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Casey L. Hanley, Ph.D.
Division of Orthopedic Devices